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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ABRAXIS BIOSCIENCE, LLC and CELGENE CORPORATION, **Plaintiffs,** **v.** **HBT LABS, INC.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Abraxis BioScience, LLC ("Abraxis") and Celgene Corporation ("Celgene Corp.") (collectively, "Celgene"), by their undersigned attorneys, for their Complaint against defendant HBT Labs, Inc. ("HBT"), allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from HBT's filing of New Drug Application ("NDA") No. 211875 ("HBT's NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Celgene's ABRAXANE® drug product prior to the expiration of United States Patent Nos. 7,758,891 ("'891 patent"), 7,820,788 ("'788 patent"), 7,923,536 ("'536 patent"), 8,034,375 ("'375 patent"), 8,138,229 ("'229 patent"),

8,268,348 ("'348 patent"), 8,314,156 ("'156 patent"), 8,853,260 ("'260 patent"), 9,101,543 ("'543 patent"), 9,393,318 ("'318 patent"), 9,511,046 ("'046 patent"), and 9,597,409 ("'409 patent"), all owned by Abraxis (collectively, the "patents-in-suit").

The Parties

2. Plaintiff Celgene Corp. is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene Corp. focuses on the discovery and development of products for the treatment of cancer and other severe conditions. Celgene Corp. is organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. Plaintiff Abraxis is a wholly owned subsidiary of Celgene Corp. Abraxis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 11755 Wilshire Boulevard, 20th Floor, Los Angeles, California 90025.

4. On information and belief, Defendant HBT Labs, Inc. is a corporation organized under the laws of the State of Delaware, having a principal place of business at 536 Vanguard Way, Brea, California 92821.

Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over HBT because of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. HBT has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, HBT is in the business of manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

On information and belief, this Judicial District will be a destination for the generic drug product described in HBT's NDA. On information and belief, HBT directly or indirectly manufactures, markets, offers to sell, and sells generic drug products throughout the United States and in this Judicial District. On information and belief, HBT has purposefully conducted and continues to conduct business in this Judicial District, including the purposeful sale and distribution of generic drug products. Furthermore, HBT's Notice Letter relies on information from prior district court litigations in this District concerning the Patents-in-Suit.[1]

7. This Court also has specific jurisdiction over HBT in connection with this matter. HBT has already taken the significant step of filing HBT's NDA seeking approval to market its infringing generic drug prior to the expiration of the patents-in-suit. HBT's NDA seeks approval to sell its generic drug throughout the United States, including in the State of New Jersey. On information and belief, HBT plans to direct sales of the infringing generic drug product described in HBT's NDA into this Judicial District, where it would cause harm to Celgene. Therefore, this cause of action arises out of HBT's contacts with the State of New Jersey.

8. The State of New Jersey has an interest in providing a forum to resolve disputes, like this one, that involve the unlawful marketing of infringing generic drug products in the State of New Jersey and harm to companies, like Celgene, that have a principal places of business in, and are doing business in, the State of New Jersey.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

[1] The referenced prior litigations from this District are *Abraxis Bioscience, LLC v. Actavis LLC*, Civil Action No. 16-1925 (JMV)(MF) (D.N.J.) and *Abraxis Bioscience, LLC v. Cipla Ltd.*, Civil Action No. 16-9074 (JMV)(MF) (D.N.J.).

The Patents-in-Suit

10. On July 20, 2010, the United States Patent and Trademark Office ("PTO") duly and lawfully issued the '891 patent, titled, "Combinations and Modes of Administration of Therapeutic Agents and Combination Therapy." The '891 patent is assigned to Abraxis. A copy of the '891 patent is attached hereto as Exhibit A.

11. On October 26, 2010, the PTO duly and lawfully issued the '788 patent, titled, "Compositions and Methods of Delivery of Pharmacological Agents." The '788 patent is assigned to Abraxis. A copy of the '788 patent is attached hereto as Exhibit B.

12. On April, 12, 2011, the PTO duly and lawfully issued the '536 patent, titled, "Compositions and Methods of Delivery of Pharmacological Agents." The '536 patent is assigned to Abraxis. A copy of the '536 patent is attached hereto as Exhibit C.

13. On October 11, 2011, the PTO duly and lawfully issued the '375 patent, titled, "Combinations and Modes of Administration of Therapeutic Agents and Combination Therapy." The '375 patent is assigned to Abraxis. A copy of the '375 patent is attached hereto as Exhibit D.

14. On March 20, 2012, the PTO duly and lawfully issued the '229 patent, titled, "Compositions and Methods of Delivery of Pharmacological Agents." The '229 patent is assigned to Abraxis. A copy of the '229 patent is attached hereto as Exhibit E.

15. On September 18, 2012, the PTO duly and lawfully issued the '348 patent, titled, "Combinations and Modes of Administration of Therapeutic Agents and Combination Therapy." The '348 patent is assigned to Abraxis. A copy of the '348 patent is attached hereto as Exhibit F.

16. On November 20, 2012, the PTO duly and lawfully issued the '156 patent, titled, "Compositions and Methods of Delivery of Pharmacological Agents." The '156 patent is assigned to Abraxis. A copy of the '156 patent is attached hereto as Exhibit G.

17. On October 7, 2014, the PTO duly and lawfully issued the '260 patent, titled, "Formulations of Pharmacological Agents, Methods for the Preparation Thereof and Methods for the Use Thereof." The '260 patent is assigned to Abraxis. A copy of the '260 patent is attached hereto as Exhibit H.

18. On August 11, 2015, the PTO duly and lawfully issued the '543 patent, titled, "Combinations and Modes of Administration of Therapeutic Agents and Combination Therapy." The '543 patent is assigned to Abraxis. A copy of the '543 patent is attached hereto as Exhibit I.

19. On July 19, 2016, the PTO duly and lawfully issued the '318 patent, titled, "Methods of Treating Cancer." The '318 patent is assigned to Abraxis. A copy of the '318 patent is attached hereto as Exhibit J.

20. On December 6, 2016, the PTO duly and lawfully issued the '046 patent, titled, "Methods of Treating Pancreatic Cancer." The '046 patent is assigned to Abraxis. A copy of the '046 patent is attached hereto as Exhibit K.

21. On March 21, 2017, the PTO duly and lawfully issued the '409 patent, titled, "Methods of Treating Cancer." The '409 patent is assigned to Abraxis. A copy of the '409 patent is attached hereto as Exhibit L.

The Abraxane® Drug Product

22. Celgene holds an approved NDA under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for paclitaxel protein-bound particles for injectable suspension (NDA No. 21-660), which it sells under the trade name ABRAXANE®. ABRAXANE® is an FDA-approved prescription medicine used for the treatment of certain hard-to-treat forms of cancer, including (1) metastatic breast cancer (after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy); (2) locally advanced or metastatic non-small cell lung cancer, as first-line treatment in combination

with carboplatin, in patients who are not candidates for curative surgery or radiation therapy; and (3) metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical compositions and methods of use and administration of paclitaxel protein-bound particles for injection, including ABRAXANE®. Abraxis owns the patents-in-suit.

23. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ABRAXANE®.

24. The labeling for ABRAXANE® instructs and encourages physicians, other healthcare workers, and patients to administer ABRAXANE® according to one or more the methods claimed in the patents-in-suit.

Acts Giving Rise to This Suit

25. Pursuant to Section 505 of the FFDCA, HBT filed HBT's NDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound), 100 mg/vial ("HBT's Proposed Product"), before the patents-in-suit expire.

26. On information and belief, in connection with the filing of HBT's NDA as described in the preceding paragraph, HBT provided a written certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("HBT's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in HBT's NDA.

27. No earlier than November 6, 2018, Celgene received written notice of HBT's Paragraph IV Certification ("HBT's Notice Letter") pursuant to 21 U.S.C. § 355(b)(2)(A). HBT's Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable,

and/or will not be infringed by the activities described in HBT's NDA. HBT's Notice Letter also informed Celgene that HBT seeks approval to market HBT's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '891 Patent

28. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

29. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed Product, prior to the expiration of the '891 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. There is a justiciable controversy between the parties hereto as to the infringement of the '891 patent.

31. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will infringe one or more claims of the '891 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States.

32. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will induce infringement one or more claims of the '891 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, upon FDA approval of HBT's NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the '891 patent and knowledge that its acts are encouraging infringement.

33. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '891 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's

Proposed Product is especially adapted for a use that infringes one or more claims of the ’891 patent and that there is no substantial non-infringing use for HBT’s Proposed Product.

34. Celgene will be substantially and irreparably damaged and harmed if HBT’s infringement of the ’891 patent is not enjoined.

35. Celgene does not have an adequate remedy at law.

36. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count II: Infringement of the ’788 Patent

37. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

38. HBT’s submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT’s Proposed Product, prior to the expiration of the ’788 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

39. There is a justiciable controversy between the parties hereto as to the infringement of the ’788 patent.

40. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will infringe one or more claims of the ’788 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States.

41. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will induce infringement of one or more claims of the ’788 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States. On information and belief, upon FDA approval of HBT’s NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the ’788 patent and knowledge that its acts are encouraging infringement.

42. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '788 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's Proposed Product is especially adapted for a use that infringes one or more claims of the '788 patent and that there is no substantial non-infringing use for HBT's Proposed Product.

43. Celgene will be substantially and irreparably damaged and harmed if HBT's infringement of the '788 patent is not enjoined.

44. Celgene does not have an adequate remedy at law.

45. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '536 Patent

46. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

47. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed Product, prior to the expiration of the '536 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

48. There is a justiciable controversy between the parties hereto as to the infringement of the '536 patent.

49. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will infringe one or more claims of the '536 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States.

50. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will induce infringement of one or more claims of the '536 patent under 35 U.S.C. § 271(b) by

making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, upon FDA approval of HBT's NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the '536 patent and knowledge that its acts are encouraging infringement.

51. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '536 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's Proposed Product is especially adapted for a use that infringes one or more claims of the '536 patent and that there is no substantial non-infringing use for HBT's Proposed Product.

52. Celgene will be substantially and irreparably damaged and harmed if HBT's infringement of the '536 patent is not enjoined.

53. Celgene does not have an adequate remedy at law.

54. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '375 Patent

55. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

56. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed Product, prior to the expiration of the '375 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. There is a justiciable controversy between the parties hereto as to the infringement of the '375 patent.

58. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will infringe one or more claims of the '375 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States.

59. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will induce infringement of one or more claims of the '375 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, upon FDA approval of HBT's NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the '375 patent and knowledge that its acts are encouraging infringement.

60. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '375 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's Proposed Product is especially adapted for a use that infringes one or more claims of the '375 patent and that there is no substantial non-infringing use for HBT's Proposed Product.

61. Celgene will be substantially and irreparably damaged and harmed if HBT's infringement of the '375 patent is not enjoined.

62. Celgene does not have an adequate remedy at law.

63. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '229 Patent

64. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

65. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed

Product, prior to the expiration of the ’229 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

66. There is a justiciable controversy between the parties hereto as to the infringement of the ’229 patent.

67. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will infringe one or more claims of the ’229 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States.

68. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will induce infringement of one or more claims of the ’229 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States. On information and belief, upon FDA approval of HBT’s NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the ’229 patent and knowledge that its acts are encouraging infringement.

69. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will contributorily infringe one or more claims of the ’229 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT’s Proposed Product is especially adapted for a use that infringes one or more claims of the ’229 patent and that there is no substantial non-infringing use for HBT’s Proposed Product.

70. Celgene will be substantially and irreparably damaged and harmed if HBT’s infringement of the ’229 patent is not enjoined.

71. Celgene does not have an adequate remedy at law.

72. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '348 Patent

73. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

74. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed Product, prior to the expiration of the '348 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

75. There is a justiciable controversy between the parties hereto as to the infringement of the '348 patent.

76. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will infringe one or more claims of the '348 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States.

77. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will induce infringement of one or more claims of the '348 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, upon FDA approval of HBT's NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the '348 patent and knowledge that its acts are encouraging infringement.

78. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '348 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's

Proposed Product is especially adapted for a use that infringes one or more claims of the '348 patent and that there is no substantial non-infringing use for HBT's Proposed Product.

79. Celgene will be substantially and irreparably damaged and harmed if HBT's infringement of the '348 patent is not enjoined.

80. Celgene does not have an adequate remedy at law.

81. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '156 Patent

82. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

83. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed Product, prior to the expiration of the '156 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

84. There is a justiciable controversy between the parties hereto as to the infringement of the '156 patent.

85. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will infringe one or more claims of the '156 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States.

86. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will induce infringement of one or more claims of the '156 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, upon FDA approval of HBT's NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the '156 patent and knowledge that its acts are encouraging infringement.

87. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '156 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's Proposed Product is especially adapted for a use that infringes one or more claims of the '156 patent and that there is no substantial non-infringing use for HBT's Proposed Product.

88. Celgene will be substantially and irreparably damaged and harmed if HBT's infringement of the '156 patent is not enjoined.

89. Celgene does not have an adequate remedy at law.

90. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '260 Patent

91. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

92. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed Product, prior to the expiration of the '260 patent, constitutes infringement of the one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

93. There is a justiciable controversy between the parties hereto as to the infringement of the '260 patent.

94. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will infringe one or more claims of the '260 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States.

95. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will induce infringement of one or more claims of the '260 patent under 35 U.S.C. § 271(b) by

making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, upon FDA approval of HBT's NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the '260 patent and knowledge that its acts are encouraging infringement.

96. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '260 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's Proposed Product is especially adapted for a use that infringes one or more claims of the '260 patent and that there is no substantial non-infringing use for HBT's Proposed Product.

97. Celgene will be substantially and irreparably damaged and harmed if HBT's infringement of the '260 patent is not enjoined.

98. Celgene does not have an adequate remedy at law.

99. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '543 Patent

100. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

101. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed Product, prior to the expiration of the '543 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

102. There is a justiciable controversy between the parties hereto as to the infringement of the '543 patent.

103. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will infringe one or more claims of the '543 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States.

104. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will induce infringement of one or more claims of the '543 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, upon FDA approval of HBT's NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the '543 patent and knowledge that its acts are encouraging infringement.

105. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '543 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's Proposed Product is especially adapted for a use that infringes one or more claims of the '543 patent and that there is no substantial non-infringing use for HBT's Proposed Product.

106. Celgene will be substantially and irreparably damaged and harmed if HBT's infringement of the '543 patent is not enjoined.

107. Celgene does not have an adequate remedy at law.

108. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count X: Infringement of the '318 Patent

109. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

110. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed

Product, prior to the expiration of the ’318 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

111. There is a justiciable controversy between the parties hereto as to the infringement of the ’318 patent.

112. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will infringe one or more claims of the ’318 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States.

113. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will induce infringement of one or more claims of the ’318 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States. On information and belief, upon FDA approval of HBT’s NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the ’318 patent and knowledge that its acts are encouraging infringement.

114. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will contributorily infringe one or more claims of the ’318 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT’s Proposed Product is especially adapted for a use that infringes one or more claims of the ’318 patent and that there is no substantial non-infringing use for HBT’s Proposed Product.

115. Celgene will be substantially and irreparably damaged and harmed if HBT’s infringement of the ’318 patent is not enjoined.

116. Celgene does not have an adequate remedy at law.

117. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XI: Infringement of the '046 Patent

118. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

119. HBT's submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT's Proposed Product, prior to the expiration of the '046 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

120. There is a justiciable controversy between the parties hereto as to the infringement of the '046 patent.

121. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will infringe one or more claims of the '046 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States.

122. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will induce infringement of one or more claims of the '046 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, upon FDA approval of HBT's NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the '046 patent and knowledge that its acts are encouraging infringement.

123. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '046 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's

Proposed Product is especially adapted for a use that infringes one or more claims of the ’046 patent and that there is no substantial non-infringing use for HBT’s Proposed Product.

124. Celgene will be substantially and irreparably damaged and harmed if HBT’s infringement of the ’046 patent is not enjoined.

125. Celgene does not have an adequate remedy at law.

126. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count XII: Infringement of the ’409 Patent

127. Celgene repeats and realleges the foregoing allegations as if fully set forth herein.

128. HBT’s submission of its NDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of HBT’s Proposed Product, prior to the expiration of the ’409 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

129. There is a justiciable controversy between the parties hereto as to the infringement of the ’409 patent.

130. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will infringe one or more claims of the ’409 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States.

131. Unless enjoined by this Court, upon FDA approval of HBT’s NDA, HBT will induce infringement of one or more claims of the ’409 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing HBT’s Proposed Product in the United States. On information and belief, upon FDA approval of HBT’s NDA, HBT will intentionally encourage acts of direct infringement with knowledge of the ’409 patent and knowledge that its acts are encouraging infringement.

132. Unless enjoined by this Court, upon FDA approval of HBT's NDA, HBT will contributorily infringe one or more claims of the '409 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing HBT's Proposed Product in the United States. On information and belief, HBT has had and continues to have knowledge that HBT's Proposed Product is especially adapted for a use that infringes one or more claims of the '409 patent and that there is no substantial non-infringing use for HBT's Proposed Product.

133. Celgene will be substantially and irreparably damaged and harmed if HBT's infringement of the '409 patent is not enjoined.

134. Celgene does not have an adequate remedy at law.

135. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Celgene respectfully requests the following relief:

(A) A Judgment be entered that HBT has infringed the patents-in-suit by submitting NDA No. 211875;

(B) A Judgment be entered that HBT has infringed, and that HBT's making, using, offering to sell, selling, or importing HBT's Proposed Product, will infringe one or more claims of the patents-in-suit;

(C) An Order be entered that the effective date of FDA approval of NDA No. 211875 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions be issued enjoining HBT and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making,

using, offering to sell, selling, or importing HBT's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining HBT, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment be issued that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of HBT's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that HBT has committed any acts with respect to the compositions and methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment be entered awarding Celgene damages for such acts;

(H) If HBT engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of HBT's Proposed Product prior to the expiration of the patents-in-suit, a Judgment be entered awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment finding this to be an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene is attorneys' fees incurred in this action;

(J) A Judgment be entered awarding Celgene its costs and expenses incurred in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: December 17, 2018

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matter in controversy involves the same plaintiffs, same drug product, and some of the same patents (United States Patent Nos. 7,820,788, 7,923,536, 8,138,229, and 8,853,260) that were at issue in the matters captioned *Abraxis Bioscience, LLC, et al. v. Actavis LLC,* Civil Action No. 16-1925 (JMV)(MF) and *Abraxis Bioscience, LLC, et al. v. Cipla Ltd.*, Civil Action No. 16-9074 (JMV)(MF). These cases were filed on April 6, 2016 and December 7, 2016, respectively, and dismissed by the Hon. John Michael Vazquez, U.S.D.J. on January 26, 2018 and October 9, 2018, respectively.

To the best of my knowledge, this matter is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: December 17, 2018

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